



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,662	11/24/2003	Hong-Mo Moon	038779/271509	6451

826 7590 12/20/2005

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,662

Applicant(s)

MOON ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 13 and 19-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-5, and 9-43 are pending in the application.
2. In the Final action mailed on June 27, 2005, claims 6-12, and 14-18 were rejected; and claims 1-5, 13, and 19-43 were withdrawn as to non-elected inventions.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 27, 2005 has been entered.

In this submission, the Applicant canceled claims 6-8, and amended claims 9 and 16.

4. Claims 9-12 and 14-18 are under consideration.

Claim Objections

5. **(Prior Objection- Maintained in part)** Claims 9 and 16 were objected to because of the following informalities: the use of the term “or” with respect to amino acid positions 15 and 123 is redundant to, or conflicts with, the “one or both” describing the asparagine residues at these positions. Although the Applicant has amended claims 9 and 16 to refer to “15 and 123,” the claim reads on a sequence in which one or both asparagines of the pre-S protein at amino acid “position” 15 and 123 have been replaced. It is suggested that the claim be amended to read on a nucleic acid wherein the one or both asparagines at amino acid - - positions- - are replaced.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 112

6. **(Prior Rejection- Withdrawn)** Claims 14-18 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an operable asserted utility or a well established utility. In view of the amendment of claim 9 to exclude linkage of the pre-S protein to the S protein, and thereby exclude embodiments requiring the secretion of the full L protein from a cell, the rejection is withdrawn.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(New Rejection)** Claims 9-12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on pIL20-pre-S vectors, and compositions thereof. The term “pIL20-pre-S” appears to read on a manipulated pIL20 vector plasmid. App., page 16 (teaching the insertion of a pre-S sequence into a pIL20 vector digested with enzymes). However, neither the application nor the relevant art appears to provide any description for the pIL20 vector referred to. While the application provides restriction maps of exemplary resulting plasmids, there is no disclosure of the sequence or of the source of the starting plasmids. Because there is no description of the initial pIL20 vector, it is unclear what is encompassed by the term “pIL20-pre-s” vector. The claims are therefore rejected as indefinite.

9. **(New Rejection)** Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1648

applicant regards as the invention. This claim reads on a recombinant vector according to claim 9 wherein the vector is transformed into a *Saccharomyces cerevisiae* cell. It is not clear from the claim if the claim is indicating that the claimed vector has been inserted into such a cell such that the claim de facto reads on a transformed *Saccharomyces cerevisiae* cell or if the claim is describing an intended use for the claimed vector. Clarification is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Withdrawn)** Claims 14-18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast transformants comprising nucleic acids encoding the double mutant pre-S protein, comprising only the pre-S region of the L protein wherein the proteins are secreted into the culture media, does not reasonably provide enablement for any transformant comprising a vector encoding any pre-S encoding nucleic acid according to claim 9. The claims were rejected based on an assertion by Applicant that transformants encoding the full length of the L protein (i.e. the pre-S and S proteins) were not capable of secreting the protein into the culture media. In view of the amendment of claim 9 such that it now requires that the pre-S sequence is not linked to the S protein, the rejection is withdrawn.

Art Unit: 1648

12. **(New Rejection)** Claims 9-12 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on pIL20-pre-S vectors, and compositions thereof. As was indicated above, these vectors are modified forms of a base pIL20 vector into which a pre-S sequence has been inserted. Thus, the pIL20 vectors are required to practice the claimed invention.

As a required element, such vectors must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the vectors. See 37 CFR 1.802. One cannot practice the claimed invention without the base plasmid. Therefore, access to them is required to practice the invention. The specification does not provide a repeatable method for readily identifying the vector without access to thereto and it does not appear to be readily available material.

Deposit of the vectors in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to

Art Unit: 1648

make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
 - (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
 - (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
 - (d) a viability statement in accordance with the provisions of 37 CFR 1.807;
- and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

13. **(New Rejection)** Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a yeast transformant comprising a pIL20-pre-S vector that secretes the mutant pre-S into culture medium wherein the vector comprises a pre-S sequence operably linked to a leader or signal sequence, does not reasonably provide enablement for methods wherein the vector does not comprise such a leader sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are drawn to any yeast cell transformed with a pIL20-pre-S vector, so long as the yeast cells perform the function of secreting the pre-S proteins into the culture medium.

In the present case, the application teaches that the use of the disclosed vectors realizes the inventions objective of producing a transformant that can secrete the pre-S sequence into the culture medium. Further, the Applicant has asserted in their arguments that the present claims are novel over the prior art in teaching the secretion of the pre-S antigen from yeast cells. See e.g.,

Art Unit: 1648

Response of Sept. 27 2005, page 8. It is noted that, although the claims require the use of a pIL20 vector comprising a pre-S sequence, there is no mention in the claims of a leader sequence such that the pre-S sequence will be secreted from the transformed cells.

However, the teachings in the art indicate that such a signal sequence is required for secretion. See e.g., Lee et al., Biochem Biophys Res Commun 303: 427-32 (teaching on page 428 the inclusion of a IL-1 N-terminal sequence for secretion of the pre-S sequence); and Lee et al., Biotechnol Prog, 15: 884-90 (teaching that the IL-1 N-terminal sequence is responsible for high rate of secretion of the target heterologous proteins from a yeast transformant). Further, it is noted that, although the application does not refer to such in the text, the plasmids used in the expression of the pre-S sequences in the Examples appear to include such an IL-1 sequence. See e.g., Figure 1 (showing a restriction map of an IL20-pre-S vector including an IL-1 sequence). While the application appears to disclose plasmid vectors including the IL-1 sequence, as there is no definition as to what is meant by pIL20 vector, it is not clear that such a sequence would be inherent to pIL20-pre-S vectors. Thus, the claims are rejected to the extent that the pIL20-pre-S vectors do not include the leader and signal sequences disclosed in the Lee references cited above.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1648

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(Prior Rejection- Withdrawn) Claims 6-12 and 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Kniskern et al. (U.S. Patent 5,614,384) in view of Takahashi et al. (Arch Virol 143: 2313-26) and of Essex (U.S. Patent 6103, 238) and O.Narhi et al. (Protein Engineering 14: 135-40). Claims 6-8 have been cancelled; the rejection is therefore withdrawn from these claims. Claims 9-12 and 14-18 are drawn to pIL20-pre-S vectors (or cells comprising such). Additionally, these claims have been amended to require that the pre-S protein is expressed in a form not linked to the S protein. As neither of these limitations appears to be met by the cited references, the rejection is withdrawn.

15. **(Prior Rejection- Withdrawn)** Claims 6-12 and 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Comberbach et al. (U.S. Patent 6,103,519) in view of Takahashi and Essex. Claims 6-8 have been cancelled; the rejection is therefore withdrawn from these claims. Claims 9-12 and 14-18 are drawn to pIL20-pre-S vectors (or cells comprising such). Additionally, these claims have been amended to require that the pre-S protein be expressed in a form not linked to the S protein. As neither of these limitations appears to be met by the cited references, the rejection is withdrawn.

16. **(New Rejection)** Claims 9, 11, 12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (U.S. 4,816,564), in view of the teachings (a) of Kniskern et al. (U.S. 5,614,384), Essex (U.S. Patent 6103, 238), and O.Narhi et al. (Protein Engineering 14: 135-40) and (b) of either of Lee et al. (Biotechnol Prog 75: 884-90) or Jang et al. (WO

Art Unit: 1648

98/54339). These claims are drawn to a pIL20-pre-S vector wherein the sequence encoding the pre-S sequence comprises Asn→His substitutions at positions 15 and 123 and is not linked to an S protein. Claims 14-18 are additionally directed to yeast cells transformed with such vectors, and which secrete the expressed pre-S proteins.

Ellis teaches a method for the production of HBV pre-S proteins in yeast cells comprising the transformation of the cell with a vector encoding the pre-S proteins. Column 4, lines 40-44. The reference teaches that the pre-S protein may be produced either in a single embodiment with the S antigen, or as a separate pre-S protein. Id., and columns 12-13 (Example 5). Further, the reference teaches the expression of the pre-S domain such that it may be included in anti-HBV vaccines as the pre-S domains have been shown in the art to provide additional benefits in the induction of anti-HBV immune responses over the S protein alone. See e.g., column 2, lines 10-35. It is noted that these teachings are supported by other teachings in the art, including teachings indicating that inclusion of the pre-S sequences improves the immune response against the S antigen. See e.g., Shouval et al., Vaccine 12: 1453-59, at 1457-58 (of record in the Jan. 2005 office action); and Jones et al., Vaccine 17: 2528-37, at 2529 and 2534-35 (of record in the June 2004 IDS). However, the reference does not teach the modification of the pre-S at positions 15 and 123 or the secretion of the proteins from the yeast cells.

The teachings of the Kniskern, Essex, and O.Narhi references have been previously described. Kniskern teaches methods of producing non-N-glycosylated versions of the S antigens of HBV. The reference indicates that such versions of the proteins, especially when recombinantly produced in yeast cells, are preferable because they reduce the chance of the generation of anti-yeast antibodies, or of the antigens being bound by anti-yeast antibodies

Art Unit: 1648

already in an animal to be immunized. Column 3, lines 33-60. Kniskern teaches that one method of producing such non-N-glycosylated antigens is through modification of the glycosylation recognition site. Column 4, lines 6-13. Kniskern teaches that the recognition sites of N-glycosylation comprise the sequences Asn-X-Ser or Asn-X-Thr, wherein the X may be any amino acid. Column 3 lines 7-15. Finally, the reference teaches that these teachings may be applied against any of the S-antigens, including the pre-S1 antigen. Column 3, lines 26-31. Kniskern indicate that any substitution may be made so long as the recognition sequence is removed. The teachings of O.Narhi, which relate to the modification of EPO such that N-glycosylation does not occur, indicates that additional benefits may be found in the form of additional stability where basic amino acids, which would include lysine and histidine, are substituted for the asparagine. Additionally, the teachings of Essex indicate that substitution of an asparagine for a histidine in an Asn-X-Ser/Thr site results in a lack of N-glycosylation at that site. See e.g., columns 6-7. From these teachings, it would have been obvious to those in the art that any amino acid, including histidine, may be substituted for asparagine to prevent N-glycosylation.

Each of the Lee and Jang references teaches a method for the production of recombinant proteins through the expression and secretion of the proteins from yeast cells. Lee, abstract; and Jang, pages 1-2. Further, each of these references indicates that the disclosed expression vectors for expression and secretion of heterologous proteins in yeast may be used to express heterologous proteins in general. Lee, abstract; Jang, page 15-16. As was indicated above (see, the rejection of claims 9-12, and 14-18 under 35 U.S.C. 112, second paragraph), it is not clear what constitutes a pIL20-pre-S vector. However, it is noted that, based on the information

Art Unit: 1648

provided in the restriction map in Figure 1 of the application, such vectors would appear to be akin to the vectors disclosed by Lee et al., *Biotechnol Prog* 75: 884-90 (page 885, Figure 1) and Jang et al. WO 98/54339 (Figure 13), except that the GH coding sequences of those vectors is replaced by the pre-S sequence. The references also teach that such expression vectors result in high levels of expression, and reduced host-cell induced degradation, of the expressed proteins. Lee, abstract, page 884; and Jang, page 12. Because these references teach the use of what appear to be pIL20 expression vectors, and suggest the use of such vectors for high level expression of proteins in yeast, it would have been obvious to those in the art to use the expression vectors of Lee or Jang in the pre-S protein production methods suggested by Ellis.

Thus, the combined teachings of the cited references render the claimed inventions obvious.

It is noted that, in the Response, the Applicant provided three arguments in traversal of the prior rejections. The first and third arguments, asserting that the prior art did not teach or suggest the expression of pre-S proteins in the absence of the S protein, and that the art did not teach or suggest the secretion of the proteins from yeast cells. However, neither of these arguments is found persuasive with respect to the rejection above. The Applicant's second argument is that the claimed vectors achieve unexpected results over the prior art in that inclusion of a pre-S protein in anti-HBV compositions improves the immunogenicity of the non-pre-S antigens. This argument is not found persuasive in view of the teachings of Ellis, or of either of the Shouval or Jones reference, as described above. Each of these three references indicates that it was known in the art that inclusion of pre-S sequences in anti-HBV vaccines resulted in improved immune responses against the HBV S antigen. Thus, the fact that the

Art Unit: 1648

inclusion of these proteins had such an effect would not have been unexpected. None of these arguments in traversal is therefore found persuasive with respect to the present rejection.

17. **(New Rejection)** Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis in view of (a) Kniskern, Essex, and O.Narhi and (b) Lee or Jang as applied to claims 9, 11, 12 and 14-18 above, and further in view of Takahashi et al. (Arch Virol 143: 2313-26). Claim 10 is directed to embodiments wherein the vector comprises the double mutant pre-S protein of SEQ ID NO: 11. The teachings of the references other than Takahashi have been described above. These references do not appear to teach the specific HBV pre-S mutant of SEQ ID NO: 1.

The teachings of Takahashi have been described previously. As was indicated in the prior actions, Takahashi teaches the full-length sequences of several Hepatitis B virus isolates, including the sequences of two isolates (represented by Protein Database accession numbers BAA32887 and BAA32860) that match the sequences provided in the present application for adr type genotypes (SEQ ID NO: 4, and SEQ ID NO: 11- which varies from SEQ ID NO: 4 at position 60, as well as by including the Asn→His substitutions). Because the teachings of Kniskern refer to the modification of HBV sequences in general, it would have been apparent that the modifications may be made to the sequence of any isolate of HBV. Thus, from the teachings of Kniskern and Takahashi, it would have been obvious to those in art to have made substitutions for the asparagine residues of positions 15 and 123. Further, because the teachings of these reference indicate that such modified forms of pre-S proteins have additional immunological benefits over the unmodified proteins, it would have been obvious for those in the art to substitute the modified pre-S sequence for the unmodified sequences suggested by

Art Unit: 1648

Ellis. The combined teachings of these references therefore render the claimed inventions obvious.

Double Patenting

18. **(New Warning)** Applicant is advised that should claim 14 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 14 reads on a yeast transformant comprising the vector of claim 9. Claim 16 purports to further limit the yeast transformant of claim 14 to embodiments wherein the asparagines of a wild-type pre-S at positions 15 and 123 are replaced with another amino acid. However, this language is redundant to the same requirement of the vector of claim 9, which is incorporated into claim 16. Thus, although claim 16 has additional language to claim 14, it does not have any additional limitations thereto. The two claims are therefore substantial duplicates one of the other.

19. **(New Warning)** Applicant is advised that should claim 9, or in the alternative claim 18, be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

Art Unit: 1648

See MPEP § 706.03(k). Claim 12 reads on a recombinant vector according to claim 9 wherein the vector is transformed into a *Saccharomyces cerevisiae* cell. Claim 9 describes the vector according to its structure. Claim 18 describes a *S. cerevisiae* cell transformed with the vector. As was indicated above, it is not clear whether claim 12 reads on the vector alone, or if the claim reads on a *S. cerevisiae* cell transformed with the vector. However, in either case, the claim is a substantial duplicate of one of claims 9 or 18.

Conclusion

20. No claims are allowed.

21. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

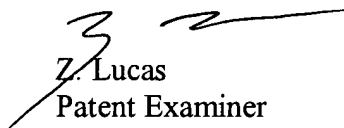
U.S. 4,959,323 and WO 99/15671. These references teach recombinant vectors encoding the pre-S HBV sequences not linked to an S protein. See e.g., U.S. 4,959,323, Example G, column 9; and WO 99/151671, Table 1, page 15 (teaching the pTECH3/WS1/S2 vector). However, the vectors do not appear to be pIL20-pre-S vectors. Thus, the references are considered redundant to the teachings of Ellis.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

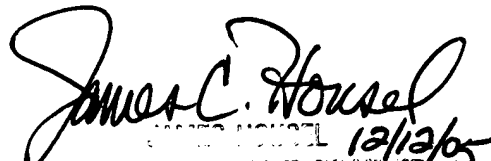
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JAMES HOWELL 12/12/05
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 1600